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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Complete If Known	
		Application Number	10/719,734
		Filing Date	November 21, 2003
		First Named Inventor	Solomon S. Steiner
		Group Art Unit	1616
		Examiner Name	Alstrum Acevedo, James Henry
Sheet 1 of 1	Attorney Docket Number	PDT 120/121 DIV CON	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
/J.H.A.A./		JONES, et al., "An investigation of the pulmonary absorption of insulin in the rat", <i>Third European Congress of Biopharmaceutics and Pharmacokinetics</i> , 1987.	
/J.H.A.A./		SAKR, "A new approach for insulin delivery via the pulmonary route: design and pharmacokinetics in non-diabetic rabbits", <i>International Journal of Pharmaceutics</i> , 86:1-7 (1992).	

Examiner's Signature	/James Alstrum Acevedo/	Date Considered	12/12/2007
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<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

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Examiner Name	Alstrum Acevedo, James Henry
Attorney Docket Number	PDT 120/121 DIV CON

Sheet 1 of 14

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
/J.H.A.A./		3,906,950		Cocozza	09-23-1975	
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		4,153,689		Hirai	05-08-1979	
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		4,866,051		Hunt	09-1989	
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		5,006,343		Benson	04-09-1991	
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		Office. <sup>2</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
/J.H.A.A./		EP	0/069/715		Draco AB	01-12-1983		
/J.H.A.A./		EP	0/122/036		Teijin Ltd	10-17-1984		
/J.H.A.A./		EP	0/237/507		Draco AB	09-16-1987		
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/J.H.A.A./		EP	0/364/235		Toyo Jozo Kabushiki	04-18-1990		
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/J.H.A.A./		5,145,684		Liversidge, et al.	09-08-1992	
		5,188,837		Domb	02-1993	
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		5,354,562		Platz	10-11-1994	
		5,364,838		Rubsamen	11-15-1994	
		5,458,135		Patton, et al.	10-17-1995	
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		5,484,606		Dhabar, et al.	01-16-1996	
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		5,514,646		Chance, et al.	05-07-1996	
		5,562,909		Allcock, et al.	10-08-1996	
/J.H.A.A./		5,577,497		Mecikalski, et al.	11-26-1996	

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		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
No translation	EP		0655237		HOECHST AG	03-26-1996		
/J.H.A.A./	EP		0748213		Inhale Therapeutic Sys	12-18-1996		
/J.H.A.A./	EP		1/114/644		Genetech, Inc.	07-11-2001		
	EP		96911738		Nektar Therapeutics	06-16-2004		

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Sheet	3	of	14	Attorney Docket Number	PDT 120/121 DIV CON

/J.H.A./	GB	2,240,337		National Research Development Corp.	07-31-1991	
/J.H.A./	JP	0149545		Taisho Pharmaceutical Co.	02-12-1992	

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/J.H.A./	A/	5,653,961		McNally, et al.	08/05/1997	
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		5,740,794		Smith, et al.	04-21-1998	
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		5,877,174		Ono, et al.	03-02-1999	
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		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		JP	363020301A		Dainichi Color and Chem	01-1998		
		PCT	0 220 958 A2		Eli Lilly and Company	05-06-1987		
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Sheet	4	of	14	Attorney Docket Number	PDT 120/121 DIV CON

/J.H.A.A./	PCT	WO 90/13285		Enzytech, Inc	11-15-1990		
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		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
/J.H.A.A./	PCT		WO 92/04069		Aktiebolaget astra	03-1992		
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/J.H.A.A./		7,030,084		Ekwuribe, et al.	04-18-2006	

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		Office. <sup>3</sup>	Number*	Kind Code* (if known)				
/J.H.A.A./	A/	PCT	WO 01/00654		Steiner	01-2001		
/J.H.A.A./	A/	PCT	WO 01/07107		PharmaceuticalDiscovery Corporation	02-01-2001		
/J.H.A.A./	A/	PCT	WO 03/057170		Emisphere Technologies	07-17-2003		
/J.H.A.A./	A/	PCT	WO 03/086345		Atrix Laboratories, Inc.	10-23-2003		
/J.H.A.A./	A/	PCT	WO 03/094951		Novo Nordisk As	11-20-2003		
/J.H.A.A./	A/	PCT	WO 04/056314		Nastech Pharmaceutical Company Inc	07-08-2004		

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		Application Number	10/719,734		
		Filing Date	November 21, 2003		
		First Named Inventor	Solomon S. Steiner		
		Group Art Unit	1616		
		Examiner Name	Alstrum Acevedo, James Henry		
Sheet	8	of	14	Attorney Docket Number	PDT 120/121 DIV CON

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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/J.H.A.A./		2005/0153874		Cheatham	07-14-2005	
		2004/0096403		Steiner	05-20-2004	
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		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
/J.H.A.A./		PCT	WO 05/089722		Biodel, Inc	09-29-2005		
/J.H.A.A./		PCT	WO 02/11676		DMI Biosciences, Inc.	02-14-2002		
/J.H.A.A./		PCT	WO 04/075919		Medtronic Minimed, Inc	09-10-2004		

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Sheet	9	of	14
		Attorney Docket Number	PDT 120/121 DIV CON

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
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Not provided		BAUER, et al. "Assessment of beta-adrenergic receptor blockade after isamoltane, a 5-HT <sub>1</sub> -receptor active compound, in healthy volunteers," <i>Clin. Pharmacol Ther</i> 53:76-83 (1993).	
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/J.H.A.A./		ENGELGAU, et al., "Screening for type 2 diabetes," <i>Diabetes Care</i> 1563(23):1-31 (2000).	
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		First Named Inventor	Solomon S. Steiner
		Group Art Unit	1616
		Examiner Name	Alstrum Acevedo, James Henry
Attorney Docket Number	PDT 120/121 DIV CON		
Sheet	11	of	14

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/J.H.A.A./		KOHLER, "Aerosols for Systemic Treatment", <i>Lung Suppl.</i> 677-683 (1990)	
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Sheet	12	of	14	Attorney Docket Number	PDT 120/121 DIV CON

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/J.H.A.A./		NAGAI, et al., "Powder Dosage Form of Insulin for Nasal Administration," <i>J. Control Rel.</i> , 1:15-22 (1984).	
/J.H.A.A./		OKUMURA, et al., "Intratracheal delivery of insulin. Absorption from solution and aerosol by rat lung," <i>Int. J. Pharmaceuticals</i> 88: 63-73 (1992).	
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Sheet	13	of	14	Attorney Docket Number	PDT 120/121 DIV CON

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OTHER ART - NON PATENT LITERATURE DOCUMENTS		
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/J.H.A.A./	WARREN, et al., "Postprandial versus preprandial dosing of biphasic insulin aspart in elderly type 2 diabetes patients" <i>Diabetes Research and Clinical Practice</i> 66:23-29 (2004).	
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Not provided		RAZ, et al. "Pharmacodynamic and pharmacokinetics of dose ranging effects of oralin versus s.c. regular insulin in Type 1 diabetic patients," <i>Fourth Annual Diabetes Technology Meeting</i> , Philadelphia, PA, 2004.	

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<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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